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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,333	12/15/2004	Yukio Goto	TB00005	1238
20462 7590 04/23/2007 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			EXAMINER JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/23/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/518,333	GOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 2,4 and 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/15/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED OFFICE ACTION**

Applicant's election with traverse of Group I invention, claims 1, 3 and 5, filed on 28 February 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Currently, claims 1-9 are pending, and claims 1, 3 and 5 are under consideration to the extent that they read on the elected invention. Claims 2, 4 and 6-9 are withdrawn from further consideration as being drawn to a non-elected invention.

#### **Formal Matters:**

##### ***Information Disclosure Statement***

Applicant's IDS submitted on 12/15/04 is acknowledged and has been considered. A signed copy is attached hereto.

##### ***Priority acknowledgement***

This application is a national stage entry (371) of PCT/US03/17744 with the international filing date of 6/5/03, which claims priority to US provisional application 60/392,176 filed on 6/27/02, which is acknowledged.

##### ***Claims***

Claim 5 is objected to as being dependent upon, in part, non-elected claims, claims 2 and 4. The applicant is required to rewritten the claim to read upon only the elected claims.

#### **Rejections under 35 U.S.C. §112:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 3 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to a method of treating IBD with said polypeptide, does not reasonably provide enablement for claims to a method of *preventing* IBD with the polypeptide (claims 1 and 3, for example). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 1 and 3 recite a method of treating or *preventing* IBD with a polypeptide (IL-18), wherein the limitation “preventing” reads on to keep the disease from happening or to cure the disease. In searching the prior art, the results of record have not established that a disease such as IBD can be prevented with IL-18. Further, the specification provides no instruction or guidance, nor working examples of in the respect to the preventing effect of IL-18 on IBD. Furthermore, prevention would necessarily mean that an individual would be given said composition, and such administration would ensure that the patient did not develop said diseases. As currently there is no decisive means to predict who would be developing the conditions, and such preventative effect has not been shown, the asserted use of *preventing* the diseases is not enabled.

Due to the large quantity of experimentation necessary to determine whether IL-18 has any preventing effect on IBD, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art, which has not established that IBD can be prevented by IL-18, and the breadth of the claims which embraces preventative effect of IL-18, undue experimentation would be required of the skilled artisan to use the claimed invention in its full scope.

**Rejections Over Prior Art:**

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Coleman et al, WO 97/24441 (provided by applicants).

Coleman discloses a human IGIF-2 polypeptide, which amino acid sequence of SEQ ID NO:2 comprises the present SEQ ID NO:1 with 100% sequence identity. Additionally, Coleman teaches that said polypeptide can be used for treating diseases/conditions including, among others, Crohn's disease or other inflammatory bowel diseases (the paragraph bridging pages 35 and 36). Therefore, the reference anticipates claims 1, 3 and 5.

**Conclusion:**

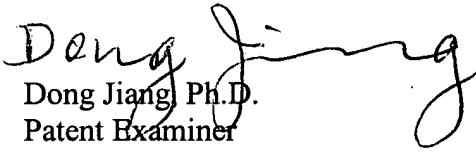
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

  
Dong Jiang Ph.D.  
Patent Examiner  
AU1646  
4/13/07